



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,917	06/11/2001	Kathrin U. Jansen	20342P	1222

7590 03/18/2005

ALYSIA A. FINNEGAN
C/O MERCK & CO., INC.
PATENT DEPT., RY60-30
P. O. BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

SCHEINER, LAURIE A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,917

Applicant(s)

JANSEN ET AL

Examiner

Laurie A. Scheiner

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/2/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claims 1-12 are pending in this application. All claims are under consideration and will be read with the elected species limitation of HPV16.

Information Disclosure Statement

The information disclosure statement filed October 2, 2003 has been considered. An initialed copy is enclosed.

Election/Restrictions

Applicant's species election without traverse of HPV16 on October 2, 2003 is acknowledged.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of

Art Unit: 1648

2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5 and 9 and 11 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Touze and Coursaget (Nucleic Acids Research, 1998, Vol. 26, No. 5).

Please see that HPV16-VLPs may be conjugated to either beta-galactosidase or green fluorescent protein (GFP) via a gene construct, respectively. Please see page 1320, penultimate paragraph for the neutralization of VLPs by antiserum to HPV-16 VLPs.

Claims 1-5 and 9 and 11 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Kawana et al. (Journal of Virology, Dec. 1998, p. 10298-10300).

Kawana et al. clearly teach that HPV-16 pseudovirions containing marker plasmids would be potentially useful in developing methods to assay virus-neutralizing antibodies and to transfer exogenous genes to HPV-susceptible cells.

Claims 1-5 and 9-11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lowy et al. (US Patent 6,599,739 B1).

Please see Example 5, at columns 30 to 31, where HPV16-BPV1/beta-galactosidase pseudotyped virions are taught. Protection for immunoprophylactic vaccines against HPV16 infection using HPV16 VLPs is monitored by testing for neutralizing antibodies against HPV16; a sample is obtained from a vaccinee and mixed with HPV16-BPV1/beta-galactosidase pseudotyped virions.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

Art Unit: 1648

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touze and Coursaget, or Kawana et al.

Touze and Coursaget, and Kawana et al. as set forth supra. Touze and Coursaget, and Kawana et al. fail in teaching the instantly claimed reporter gene construct:VPL ratio. However, limitations drawn to specific construct:VPL ratios represent obvious modifications related to establishing optimal reaction conditions. Such parameters in this art would be determined by routine experimentation. In re Aller et al, 105 USPQ 233 (CCPA – 1955).

Both Touze and Coursaget, and Kawana et al. fail to teach a beta-lactamase gene construct as required by claim 12. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a beta-lactamase gene for the beta-galactosidase gene of either Touze and Coursaget or Kawana et al. since the respective enzyme reporter genes are known functional equivalents.

With respect to claim 10, neither Touze and Coursaget nor Kawana et al. teach an assay to determine if anti-HPV neutralizing antibodies are present in human serum.

Rather, Touze and Coursaget, and Kawana et al. teach an assay to determine if anti-HPV neutralizing antibodies are present in mouse serum. However, Kawana et al. clearly state that HPV-16 pseudovirions containing marker plasmids would be potentially useful in developing methods to assay virus neutralizing antibodies. Thus, it is clear that Kawana et al's focus is the development of methods to assay anti-HPV neutralizing antibodies in human serum since HPV-16 is a major risk factor in the development of cervical cancer in women.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Laurie Scheiner/LAS
March 12, 2005



Laurie Scheiner
Primary Examiner
Art Unit 1648